BOKS in Revere

Detailed Protocol

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Study PI: Dr. Elsie Taveras

Chief, Division of General Academic Pediatrics, Department of Pediatrics
Massachusetts General Hospital for Children

Co-Investigators and Study Staff

- Dr. Rachel Whooten (Co-I)
  Research Fellow in the Division of General Academic Pediatrics, Massachusetts General Hospital for Children and Fellow in Pediatric Endocrinology, Massachusetts General Hospital for Children
- Christine Horan, MPH
  Project Manager, Massachusetts General Hospital for Children
- Research Assistants:
  Anna Nicole Dartley, Brian Kelter, Ines Castro Rosillo, Casey Crisco, Alanna Cruz-Bendezu, Michael Duggan, Vanessa Gonzalez, Camille Harris, Brandy Jean Pierre, Wesly Lima, Grace Lovell, Zazil Mardones, Karolyn Moni, Giselle O'Connor, Lydia Polley

I. Specific Aims:

School-based physical activity interventions are an area of interest in the field of childhood obesity prevention. Preliminary evidence suggests that these efforts may have a positive impact on child health, however there is large heterogeneity in interventions. This study evaluates the outcomes of a widely available school-based physical activity program, with the primary research question addressing the efficacy of a before school program – as delivered in partnership with schools – in improving indicators of child wellbeing as well as measuring implementation and feasibility.

Phase I

The primary specific aim is to perform a qualitative evaluation of child participation in a before school physical activity intervention through:

a. Interviews with parents to obtain a detailed view of what barriers parents endorse to physical activity and the role of school-based programming in overcoming these barriers

b. Standardized structured physical activity observation of physical activity

Phase II

The primary specific aims are to examine the extent to which the physical activity intervention, compared to the control condition, results in:

c. Change in BMI and BMI z-score over a 12-week period.
d. Change in cognitive function and child-reported quality of life.

The secondary aims are:

a. To evaluate the impact of program participation on school-collected outcomes, including grades, attendance, and disciplinary reports.
b. To objectively measure student levels of moderate-vigorous physical activity in intervention sessions.
c. To obtain baseline and follow-up assessment via parent report regarding demographics, family and child health history, and health behaviors such as child sleep, screentime, physical activity and parental physical activity support.
d. To assess the implementation of the BOKS physical activity program in Revere, MA, with regard to Reach, Efficacy, Adoption, and Maintenance as well as feasibility and acceptability.

II. Background and Significance

Childhood obesity and overweight has been an issue of national concern over the past decade, with recent estimates placing 1 in 3 children in either category.[1] This has significant current and future health implications for these children, with higher rates of chronic health conditions early in life as well as increased risk of depression, low self-esteem and bullying.[2]

Targeted efforts to prevent childhood obesity are a public health priority, and physical activity is an ideal candidate for intervention. It is associated with lower body mass index and decreased obesity-related comorbidities in children[3,4], as well as improved academic performance[5], self-esteem[6], and depressive symptoms[7]. Physical activity habits track throughout the life course, and health benefits persist later in life as well[3].

Despite this wide array of benefits, the majority of children do not receive an adequate amount of physical activity [8]. Schools overall do not promote physical activity and most children receive little physical activity outside of the school setting. Multiple barriers exist to school-based physical activity including resources and perception of benefits[9]. Despite these barriers, schools represent an important setting in improving child activity levels as they have existing infrastructure and an equitable reach in affecting child health. The literature supports a

role for school-based interventions, although more evidence is needed on how best to implement these efforts into schools in sustainable ways.[10,11]

This study is designed to assess the efficacy of a pre-existing school-based physical activity program, BOKS ("Build Our Kids Success"). BOKS is a before-school physical activity program that is currently present in over 2500 schools nationwide and internationally. Through this program, children in grades K-8 participate in before school physical activity sessions. Trained volunteers lead each session using a core curriculum developed by the BOKS leadership team that includes a warm-up game followed by activities such as relay races or obstacle courses, with a focus on a new "skill of the week" each week. In prior research, BOKS has been shown to improve child BMI as well as measures of social-emotional wellness over the 12-week program.[12]

Prior studies of physical activity interventions raise questions on whether the programs are sustainable and feasible following the end of the study period. The use of a pre-existing physical activity program aims to overcome these concerns. Additionally, by examining our primary and secondary outcomes in the BOKS program, we are evaluating the effect of the program as implemented in a real-world setting. Given the large reach of this program, the findings from this study are potentially generalizable to a larger population of students who are participants nation-wide.

III. Study Populations and Recruitment

Setting and Study Population

Students will be recruited within each of the three schools for participation in the BOKS before-school physical intervention. The participating schools include 1 middle school (541 enrolled students) and 2 elementary schools (494 and 370 enrolled students each). A flyer will be sent home with all children for program participation and parental consent/child assent for research trial participation. Target recruitment is 120-150 students total in the Spring 2018 session (40-50 per school) and 120-150 students in in the Fall 2018 session (40-50 per school), for total N=240-300. Students are eligible for participation if they are in grades K – 8 with enrollment in BOKS program. The inclusion of a wait-list control group is to ensure equipoise, and that all interested students have the opportunity to participate in the physical activity program.

Revere is a diverse mid-sized city north of Boston, MA.[13,14] Within the Revere School District, 55.6% of enrolled students speak a first language other than English and 37.7% are from economically disadvantaged families[15]. The pediatric and adult populations both bear a high burden of chronic disease, with rates of obesity and its related comorbidities that are higher than the statewide-average.[16] Residents cite inactivity and obesity among the largest problems

facing the community.[16] As such, this intervention is targeted towards providing equitable access to physical activity opportunities in a population with a demonstrated need.

Recruitment

Phase I

For the qualitative interviews, we will recruit parents from students who participated in the Fall 2017 BOKS program that was independently initiated at Paul Revere Innovation School. An introductory letter and fact sheet will be sent home with participating students, in which students will be asked to return the form if their parent is interested in participating in a phone interview (Appendix 5). If goal sample size is not obtained within Fall 2017 enrolled students, the same procedure will be repeated with Spring 2018 participants.

Students will be asked to return the signed forms to their BOKS trainer, and forms will be given to research staff to initiate contact with parents. We will contact parents up to three times over two weeks before considering them missed contacts. If a parent consents to the interview but cannot complete the full interview at the time of the call, we will schedule a follow-up time to complete the interview. We plan to complete approximately 10-20 total parent interviews (mothers or fathers) for this phase of the study. The interview will last approximately 20-30 minutes.

Phase II

For the intervention, we will recruit participants from the three participating schools: Paul Revere Innovation School, Beachmont Veterans Memorial School, and Garfield Middle School. All enrolled students will be eligible for participation in the program.

Students are eligible for participation in BOKS if they are (a) enrolled in the school in grades K-8 with (b) signed BOKS parental release form. In the school that independently held BOKS in Fall 2017, preference will be given to students who have not yet participated. Beachmont Elementary will limit participation to 1st through 5th grades as kindergarten students follow a different schedule.

Spring 2018 Session

For Beachmont Elementary and Garfield Middle School:

All students will receive the BOKS Registration packet approximately 3-4 weeks before their schools' planned start date that will include the following below. Recruitment information will explain that we are interested in better understanding the effects of physical activity programing on child physical health, quality of life, and school performance.

(1) Letter introducing the BOKS program and the research study
(2) Fact sheet answering key questions regarding the program and study
(3) BOKS Registration form

Children will be instructed to return the BOKS Registration Form if they would like to participate in the BOKS program. Once the BOKS Registration Form is received, children will then receive Research Consent Form in school to take home for their parents to review, to be completed if they would additionally like to participate in the BOKS study. All forms should be submitted approximately 1-2 weeks before the start of the Spring 2018 program.

In order to ensure equal access to the program, participation in the BOKS program will be by lottery and not first-come, first serve. This decision was made in conjunction with school principals to not give preference to students who turned in forms first. All children with completed BOKS registration forms will be entered in the lottery. The lottery is held in partnership with schools and independent of the research process, and will be held following return of BOKS registration forms. Children may participate in BOKS without participating in the research study. If registration does not exceed 50 students for the Spring 2018 session, there will be no waitlist control group or need for randomization.

See schema for detailed timeline.

For Paul Revere Innovation School:

As described above, this school has a pre-existing BOKS program that is independent of the research intervention and occurs as part of school-wide before school enrichment programs. Per school preference, enrollment target is approximately 40-50 students. Within this school, enrollment in the BOKS program occurs through standard school procedures for before school enrichment enrollment. Once the school has confirmed their enrollment for the Winter/Spring 2018 session, enrolled students will receive documents specific to Paul Revere, including:

1) BOKS study Introduction letter and Fact Sheet (Appendix 12a)
2) Research Consent Form (Appendix 12b)

As there will be no control group and no lottery for enrollment within this school, these documents are modified from those distributed to the other two schools and will only cover the research evaluation (not randomization and enrollment process).

Fall 2018 Session

Modifications will be made to Fall 2018 enrollment procedures based on discussions with schools as well as experience with Spring 2018 session. As program enrollment did not reach capacity in Spring 2018, no

lottery was held and all interested students were able to participate in the program. As a result, there was no wait list control group.

In discussion with participating schools, first-come, first-serve registration will be used for Fall 2018 for consistency and no lottery will be held. If the BOKS program does not reach capacity, program registration will be accepted until program is full (40-50 students). To ensure equal access, preference will be given to students who have not previously participated in the BOKS program. In discussion with school principals, a poster (Appendix 14) will be added to increase recruitment.

In order to ease the burden of paperwork distributed via the schools, paperwork will be distributed in the following order:

1. Follow-up Letter to Previous Participants (Distributed in schools **only** to **consented study participants,** in envelope with student's name on it) – Appendix 15
2. Introductory letter and Fact Sheet, with Interest Form for students to return if interested (Distributed to **ALL** students) – Appendix 16
3. BOKS registration (Distributed **only to students who return Interest Form**, to be returned prior to program start) – Appendix 6b

Consent

For Phase I of this study, parents will be consented over the phone for a qualitative interview. Verbal consent will be recorded and the date, time, and initials of the research staff will be recorded as well. We believe that verbal consent is warranted as this is a minimal risk study. A fact sheet will be given to students during or after BOKS program participation to be sent home. Parents will be asked to return the form if they are interested in being contact for a telephone interview. This fact sheet will inform parents about the study so that they may have an opportunity to ask questions prior to consenting for participation. (Appendix 9)

For the structured observation, we will not be collecting any personal information. The fact sheet will provide a description of the structured observation and contact information if parents have additional questions. Parents will also be given the dates of the observation so that parents have the option not to have their child participate on that day, if desired. The observation will follow the SOFIT protocol, in which student activity (e.g. lying, sitting, standing, vigorous, etc.), teacher involvement (e.g. promoting fitness, demonstrating fitness, managing, observing, etc.) and lesson context (e.g. general content, knowledge content, physical education motor content, etc.) are recorded at 10-second intervals (followed by 10-seconds for recording) for the duration of the session. Gender distribution and total participants within the session is noted but no additional individual information is collected. (See Appendix for Data Collection Form).

Spring 2018

For Phase II of this study, all parent handouts (Fact Sheets, Registration Form, Introduction Letter, Consent Form) will be available in the 4 most common languages within the Revere school district: English, Spanish, Portuguese, and Arabic. Written consent will be obtained and parents will be provided an addressed and stamped envelope to return consent form to the research team. Parents will be given a second consent form for their records (Appendix 6c).

For schools without a pre-existing BOKS program, parents will complete and return the Program Registration Form if they are interested in enrolling their child in the BOKS program. For schools with a pre-existing BOKS program in which students are already registered, study consent will include sharing of registration form with the research team. For all schools, parents who enroll their children in BOKS will complete the Research Consent Form (sent home after program registration) if they accept participation in the BOKS study. Children can participate in BOKS without participating in the research study. Parents will return the Consent Form directly to the research team in an addressed and stamped envelope to be mailed. Given that schools work within a fixed timeline with limited flexibility of changing program schedule and potential delay in delivery of consent forms via mail, students may also turn research consent forms in sealed envelopes to school to be picked up by research staff and transported to MGH. In further discussion with principals, they recommended this additional option as well for consent form return to minimize burden on parents in the event they cannot make it to the post office/mail box. Families may also receive a second consent form if requested.

Completed consent form to be stored in a locked file as well as documented in REDCap, including date of consent. The PI/Project Manager will review consent forms for accuracy and completeness, in addition to monitoring study process and outcomes regularly.

Given the different study recruitment between schools based on school needs, different consent form and accompanying letters will be distributed to students based on school (Appendix 6 for schools without pre-existing programs; Appendix 12 for schools with pre-existing programs).

Fall 2018

For students who consented for research study participation in the Spring 2018 BOKS session, research consent included Fall 2018 study participation (collection of baseline and follow-up measures) regardless of Fall 2018 BOKS program participation. While these participants will not be re-consented this Fall, these children will again be offered the opportunity to participate in the BOKS program and program materials sent home will give the option of declining study

participation if desired. A letter will be sent home to consented participants explaining these options (Appendix 15).

For students who are newly enrolled in the BOKS program, consent procedures for Fall 2018 session will be identical to Spring 2018 procedures with four exceptions:

(1) Fall 2018 study materials will only be distributed in English and Spanish. Few study materials were returned in Arabic or Portuguese. In cases where documents in these languages were sent home along with English language documents, parents often returned the English language version.
(2) One general consent form will be developed for all participating schools (Appendix 18) that will be sent home with new version of Letter with Consent Form (Appendix 17). School-specific fact sheets will be sent home with exact program details (Appendix 16). The consent form will provide the range of BOKS program dates for the fall for all schools involved in the study. Unexpected circumstances (ie inclement weather, school closures) may arise and modifications to session times may arise, making it impractical to include the exact session dates on the consent form.
(3) Enrollment for Fall 2018 will be first-come, first-served. While consent for the Spring 2018 included a lottery and the potential of randomization to a wait-list control group that would participate in the program in Fall 2018, this will not be included in the Fall 2018 consent. First, enrollment in the Spring 2018 did not require a lottery as enrollment was within program capacity. Second, as funding for the BOKS program is only guaranteed through the Fall 2018 session, there is no additional session for students to be randomized to.
(4) As consent does not involve randomization, consent forms will be accepted until start of baseline data collection. In response to feedback from schools and trainers, two options for return of consent forms are provided. Consent forms may be returned either in stamped, addressed envelope via mail OR in sealed manila envelope provided to BOKS trainer, to be picked up by study staff and delivered directly to secure location within MGH.

Child participation in this study involves minimal risk and children will not be asked to do anything that their parent has not provided consent for. For children completing the cognitive and quality of life measures (>8 yo), trained CRCs will provide an opportunity for verbal child assent using a standardized assent script prior to completing the measures. Child assent will be recorded on Child Measurement form (form amended to add this field, including date, time, and initials of the individual obtaining assent), and measures will not be taken if child does not

assent. All assent information will be stored in a locked file at 125 Nashua St as well as documented in REDCap.

Remuneration

For participating in the qualitative interviews, parents will receive $10 Target gift card for completion of the telephone interview. A letter will accompany all gift cards home to parents (Appendix 8).

For completing the baseline and follow-up surveys for the intervention, parents will receive a $5 Target gift card that will be mailed to them following receipt of each survey ($10 total).

Students in the intervention and control group will receive $2 following completion of baseline measures and $2 following completion of follow-up measures within both the Spring and Fall 2018. These incentives will be mailed to the students' homes, along with either a "Thank You" letter (Appendix 13a) upon completion of baseline assessment or a "Study Completion Certificate" (Appendix 13b) upon completion of follow-up assessment. Additionally, through the standard BOKS program, intervention students receive small incentives (key chains, stickers, etc.) as well as a BOKS t-shirt. Students in both the Spring 2018 and Fall 2018 sessions will receive these incentives at the time of their participation in the BOKS program. The BOKS incentives are a standard component of the BOKS program.

Randomization

Spring 2018

From the sample of all complete registration forms (regardless of research study participation), children will be entered in a lottery that will determine whether students will be randomized to (a) participate in the intervention in Spring 2018 (regardless of study participation) or (b) participate in a wait-list control group in Spring 2018 (if consented to the study) and the intervention in Fall 2018 (regardless of study participation) or (c) wait list. In partnership with schools, a study team member will receive a de-identified list of BOKS registrants, and will randomize registrants to one of the three conditions to assist schools in lottery process. This is structured this way as program implementation is supported by a community health implementation grant and study staff is assisting in program implementation separate from the research evaluation. Sibling pairs will be randomized together to minimize burden on families. We will block the randomization to have a roughly equal representation of each gender within each group.

Our goal recruitment is 80-100 students per school for the Spring 2018 session, with 40-50 to participate in the intervention group and 40-50 to participate in the wait-list control group. If more than 80-100 students are interested in the program and enter the lottery, a third group

will be randomized to a wait list for the Fall 2018 group. If less than 80-100 students are interested in participating in the BOKS program, randomization will be weighted towards filling the intervention group in order to allow children access to this program. The children that are randomized to the wait list control group will have priority for registration for the Fall 2018 session. If any students who were randomized to Spring 2018 drop out after randomization, these children in the Wait List group will be randomly selected for Spring 2018 participation. A letter will be sent home to all parents 1 week prior to program start detailing group assignment (Appendix 7). If registration does not exceed 50 students for the Spring 2018 session, there will be no waitlist control group or need for randomization.

Randomization will not occur within the school with a pre-existing BOKS program.

Fall 2018

Randomization will not be included in Fall 2018 enrollment procedures. Enrollment in the BOKS program will be first-come, first-come at each school with goal enrollment of 40-50 students at each school (120-150 students total), with preference given to students who have not yet participated in the BOKS program. This decision was made with input from school principals and BOKS session leaders.

IV. Study Visits and Data Collection

This study is a collaborative effort of key stakeholders, including Revere community health infrastructure (RevereCARES), the Revere School District, the BOKS program, and this research team. Initial conversations with stakeholders began in Summer 2017, following which an internal implementation grant was awarded in October 2017 from the MGH Executive Committee on Community Health, with the aim of improving health equity. Additional conversations have continued with stakeholders regarding planned study procedures, pending IRB approval.

Phase I

In the initial qualitative phase of the study, we will perform semi-structured qualitative interviews with parents to assess barriers to physical activity and the role that school based interventions may play in reducing barriers. Parents will be recruited from those students participating in an independently initiated Fall 2017 BOKS program occurring in one of the participating schools. If recruitment goal is not met, parents will be recruited from the Spring 2018 BOKS session.

A handout will be sent home with students participating in BOKS with a fact sheet explaining the study and a form to return if parents would like to be contacted for a telephone interview. After obtaining verbal consent via telephone, parent will be asked a series of questions related to their perceptions of the BOKS program as well as barriers to physical activity (See Appendix 1). The interview will be led by trained research staff and will take about 20-30 minutes.

In addition, we will perform an observation of a BOKS session using SOFIT, a structured observational tool for physical activity.

Phase II

Prior to planned intervention start, volunteers from each school (teachers, parents, or school nurses) will receive formal training regarding the BOKS curriculum in. This training will be conducted by the BOKS program per their standard procedure and will occur at one of the participating schools. Volunteers will be recruited from interested individuals within each school (identified by the principals; may include teachers, school nurses, or parents).

The intervention sessions will occur before school, 3 days/week, lasting 30-60 minutes, for 12-15 weeks (with schedule and start date to be determined by school principal, in accordance with school resources and needs). Two trained volunteers will be present for each physical activity session, with approximately 40-50 students total per session. In accordance with BOKS regulations, trainers must be CPR certified and parents will have signed a release for program participation (in addition to study consent). All physical activity sessions will occur within school gymnasiums. Trainers will not participate in data collection.

At the beginning of the BOKS program (within one week of the study start at schools with 12 week program or within 3 weeks of study start in schools with 15 week program), each intervention group and control group student will have height and weight measured by trained research staff at the school in a setting that ensures student privacy. Students will also complete a validated measure of pediatric quality of life as well as one iPad-based cognitive tasks (anticipated total time 30 minutes). Trained research staff will be present to guide students through the assessment (see Appendix 3). Evaluations will occur at the time of a non-academic school period or within BOKS programming. Intervention and control group children will not stay after-hours for completion of measures. These measures will be repeated at 12-week follow-up (+/-1 week). Although one school plans to continue for 15-weeks due to their academic calendar, follow-up measurements will occur at approximately 12-weeks intervals in all schools. Schools will provide student report cards/progress reports, attendance, and disciplinary reports, only for students with signed parental consent for the research study. These measures will be completed in both groups in both the Spring 2018 and Fall 2018

sessions, regardless of group assignment. If students are not present in school at designated measurement periods, individual outreach attempts may be made.

Parents will also complete a survey at baseline and follow-up that includes questions assessing information such as demographic information, parental support for physical activity and child health/behaviors (such as child pubertal status, baseline physical activity, screentime, and sleep behaviors; See Appendix 4). Surveys will be mailed to the parents at both time points. Additional copies of the survey may be sent if the original is not returned within 1-2 weeks of its anticipated receipt. If schools permit, at follow-up, surveys may also be sent home with the child to ensure the parent receives it and returned to the school, if more convenient for the parent than to return by mail.

Only **one** baseline/follow-up parent survey will be collected per participating student. If a parent completed the baseline or follow-up survey in the Spring 2018 session, they will not receive the survey in the fall. If the parent did not complete the survey **or** is a new participant, they will receive the parent survey at the start and end of the Fall 2018 session.

We will assess fidelity of the curriculum through several measures measures in both BOKS sessions (Spring and Fall). During the 12-week physical activity session, each student will wear a waist-based pedometer for at least one session to provide an objective measure of physical activity. We will also conduct a validated, structured observation of the physical activity (SOFIT). We will also record attendance at BOKS sessions. In order to maximize attendance at programs, school principals have requested that enrollment information specify that >80% attendance at sessions is expected.

V. Measures

Trained research assistants will obtain measures detailed below (see **Table**) at baseline and 12-week follow-up in intervention group and controls. Anthropometrics will be obtained in all students, while cognition and quality of life measures will be obtained only for students ≥8 years old. We will also obtain a parent survey at baseline and follow-up for all participants. In addition, ten to twenty parents will be recruited for a qualitative component will be used for future hypothesis-generation and intervention development (edited here for consistency with other parts of protocol, which states recruitment of 20 parents). Outcomes denoted below by ***** are primary outcomes.

Physical activity session evaluations will occur during the 12-week BOKS program. Each child will wear an accelerometer for 1-3 sessions (frequency to be determined by RA availability and scheduling; all students will have same number of accelerometer sessions within each school).

Outcome	Measure

PRIMARY OUTCOMES (Appendix 3)	
Anthropometrics	
Body Mass Index (BMI)	*Kg/m^2, using height and weight measured by trained personnel using scale and Seca® stadiometer.*
BMI z-score	*Calculated BMI will be assigned z-score based on student's age and sex, using standards established by the CDC 200 growth charts.*[17]
Cognition*	
Executive Function & Attention	One measure of ability to plan, organize, and execute goal-oriented behaviors in the context of conflicting stimuli, included in the NIH Toolbox[18]: • Flanker Inhibitory Control and Attention Test[19,20]
Quality of Life*	PedsQL 4.0 (Child Self Report): *validated 23-item questionnaire assessing physical, emotional, social, and school functioning, use in ages 5-18.* [22]
SECONDARY OUTCOMES	
School Performance	
Academic performance	*Grade point average (available for grades 4-8) of grades for reading, math, and science classes.*
Attendance	*School record of student attendance and disciplinary reports, obtained with parental consent.*
Disciplinary Reports	
Parent Questionnaire (Appendix 4)	
Demographics	*Parent self-report of relationship to child, age, height, weight, race/ethnicity, household income, and child's age/sex.*
Family and child health history	*Parental report of family history of cardiometabolic disease (diabetes, cardiovascular disease, hypertension) and child medical history (asthma, overweight/obesity).*
Pubertal status	Parental report of Tanner staging: *validated scale of parental report of child pubertal progression.*[23]

Sleep hygiene	Parental proxy report of sleep duration: *1 question from Pediatric Sleep Questionnaire.[24] Method previously used in this age group.*[25]
Screentime	Parental proxy report of screentime: *2 questions assessing (1) time spent watching TV/ videos, (2) whether child has a TV in their room, and (3) computer/tablet usage. Method previously used in this age group.[25]*
Physical Activity Support	Activity Support Scale: *Parental self-report containing 7-items that assess (1) logistic support and (2) modeling of physical activity behaviors. Valid and reliable measure of parental support for physical activity.*[26]
Child Physical Activity	Parent proxy report of child physical activity: *Weekly frequency of physical activity >60 minutes/day. Method previously used in this age group[25].*
Physical Activity Session Evaluation (to occur during program)	
Objective assessment of MVPA delivered via intervention	*Simultaneous monitoring of students participating in physical activity session via accelerometers (1-3 sessions total per child)*
Attendance at Sessions	*Attendance will be taken at each BOKS session.*
Physical Activity Observation (Appendix 2)	*Performed using SOFIT, a validated and structured observation of physical activity sessions for children.*
Parent Qualitative Interview (Appendix 1)	*Targeted phone interview with 10-20 parents, addressing (1) reasons for participating in and benefits of physical activity intervention, (2) beliefs regarding and barriers to physical activity, (3) experience with pediatrician regarding physical activity counseling, and (4) female-specific barriers and benefits of physical activity*

VI. Data Analysis

The analyses will be carried out with the child as the unit of analysis. All data will be de-identified upon collection and entered into Redcap® for data management. Distribution of participant characteristics will be analyzed using F tests from 11-way ANOVA and $\chi 2$ tests. Our

primary analyses will be based on change from baseline to follow-up with each outcome variable, with comparison performed between intervention and control group at each time. For all continuous variables, we will use t-tests for initial comparison between groups, followed by linear regression to control for potentially confounding variables (age, sex, school, SES) or potential effect modification (program attendance/MVPA level, parental PA support, baseline PA level, baseline BMI). For all binary variables, we will use Chi Square tests to evaluate for differences between groups at baseline and follow-up, followed by logistic regression to evaluate for confounding or effect modification. All analyses will be done in SAS under the guidance of a statistician.

Transcriptions from qualitative interviews will be reviewed by two study staff members to identify themes. Results from structured physical activity observation will provide descriptive statistics regarding individual program content and will be used as a measure of program implementation along with accelerometer data.

VII. Monitoring and Quality Assurance

Data security & privacy:

Paper data collection forms will be stored in a locked and secure facility only accessible by research staff at MGH in the Division of General Pediatrics at 125 Nashua St, 8th Floor, Boston, MA 02114. All data collected and recorded on paper forms will be entered into a Partners supported REDCap database. Only approved study staff will have access to identifiable information and the linking code. Research staff will track all communication made with parents this database including parent was contacted about the study, if the child was eligible and interested in participating, and demographic information (age, gender, parent contact info). This database will be housed on the Partners network and accessible to only IRB approved study staff.

The NIH Toolbox data will be stored on password protected iPads. The NIH Toolbox iPad application is encrypted and sends data exports (in .csv format) and participant reports (in .txt format) via secure email.

All collected data will be identified with a subject ID number only so that it cannot be matched with an individual child.

For the qualitative portion of the study, telephone interviews with parents will be recorded. To protect confidentiality, these recordings will be stored in a Partners SFL, a HIPAA compliant and encrypted format.

Maintaining the integrity of the technology

- Research assistants and health educators will be ready to assist participants if they encounter any technical problems during the study. A support telephone number and email address will be made available to participants.
- Log of all technical difficulties will be maintained on the study database.

Monitoring and Quality Assurance

- The project manager, under direction of the Principal Investigator will monitor the study data regularly. The study staff will be appropriately trained, and the project manager will supervise data collection, storage and maintenance. The project manager will also regularly review of the accuracy and completeness of case report form entries, source documents, and informed consent.
- Research staff will evaluate the completeness of signed consent forms and questionnaires.
- The project manager will ensure that all paperwork is securely stored. The PI will ascertain appropriateness of security of all documents on a monthly basis.

Use of data

- Data collected will only be used for research purposes. Participants' anonymity will be protected in any publication of findings.
- All collaborators will be from within the Partners system.
- The only exception for data to be sent outside of Partners will be the use of an outside transcription service for the Qualitative component (Phase I) of this study. Files shared with the transcription service will be identified only by participant ID. The recordings and transcripts will be sent using a secure and encrypted online portal.

VIII. Risks and Benefits

Risk and Discomforts

As children will be physically active during these sessions, there is a risk of injury from physical activity. We do not expect these risks to be any greater than physical education lessons, which is standard practice within elementary and middle schools. It is also standard practice of schools and the BOKS program that parents sign a release form prior to allowing their child to participate in physical activity programs. Additionally, this program is currently existing in >2000 schools throughout the US and internationally, and the contents of this physical activity intervention is not unique to this research study.

It is possible that assessing weight and height may be sensitive for some children, and that answering the parental survey may be sensitive for some parents.

A breach in participant privacy and confidentiality is also a possible risk. To minimize this risk, we will use the minimum amount of PHI necessary for the proposed research. Participants are

given an artificial study ID number that is linked through separate coding. Only study staff can link participant study ID numbers to PHI. All paper data is secured in locked file cabinets. All electronic data is secured in password protected files on computers with virus software enabled, with minimum necessary access.

Any time participant data will be transferred between MGH and a collaborator or vendor, it will be sent through a Partners approved method (i.e. Dropbox Enterprise, Syncplicity, etc).

Benefits

Potential Benefits to Participants:

Based on prior research with school-based physical activity programming as well as the BOKS program, participants in the BOKS program may benefit from improved health outcomes from increased physical activity, as well as improvements in social-emotional wellness. Students will be able to participate in the BOKS program if they do not participate in the study, so this benefit is not unique to study participation.

Potential Benefits to Society:

This study may also provide more insight on innovative methods for the implementation of physical activity interventions for children.

Appendices:

Appendix 1: Qualitative Interview Script

Appendix 2: PA Observation Form

Appendix 3: Child Measures (including PedsQOL, NIH Toolbox)

Appendix 4: Parent Measures

Appendix 4a: Parent Measures Intro Letter

Appendix 4b: Parent Measures Reminder Letter

Appendix 5: Intro letter and Fact Sheet Phase I

Appendix 6: Intro letter and Fact Sheet Phase II

Appendix 6b: BOKS Registration Form

Appendix 6c: BOKS Phase II Consent Form

Appendix 6d: BOKS Phase II Consent Form Accompanying Letter

Appendix 7: Enrollment Letter

Appendix 8: Reward Letter

Appendix 9: Phase I Consent Script

Appendix 10: Child Assent Script

Appendix 11: Study Schema

Appendix 12a: Intro Letter and Fact Sheet Phase II – Paul Revere

Appendix 12b: BOKS Phase II Consent Form – Paul Revere

Appendix 13a: Child Thank You Letter

Appendix 13b: Child Study Completion Certificate

Updated Appendices for Fall 2018 Session

Appendix 14: BOKS Poster

Appendix 15: Follow-up Letter to previous participants

Appendix 16: BOKS Intro Letter, Fact Sheet, Interest Form

Appendix 17 - BOKS Letter with Consent Form (Fall 2018)

Appendix 18: BOKS Fall 2018 Consent Form

1. "Childhood Obesity Facts". Division of Population Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control. (Accessed 8/17/17, at https://www.cdc.gov/healthyschools/obesity/facts.htm.)
2. Overweight in Children. American Heart Assocation. (Accessed 8/17/17, at http://www.heart.org/HEARTORG/HealthyLiving/HealthyKids/ChildhoodObesity/Overweight-in-Children_UCM_304054_Article.jsp - .WZXeAMaZNE5.)
3. Sallis JF, Prochaska JJ, Taylor WC. A review of correlates of physical activity of children and adolescents. Med Sci Sports Exerc 2000;32:963-75.
4. Dencker M, Thorsson O, Karlsson MK, et al. Daily physical activity related to body fat in children aged 8-11 years. J Pediatr 2006;149:38-42.

5. Donnelly JE, Hillman CH, Castelli D, et al. Physical Activity, Fitness, Cognitive Function, and Academic Achievement in Children: A Systematic Review. Med Sci Sports Exerc 2016;48:1223-4.
6. Liu M, Wu L, Ming Q. How Does Physical Activity Intervention Improve Self-Esteem and Self-Concept in Children and Adolescents? Evidence from a Meta-Analysis. PLoS One 2015;10:e0134804.
7. Kremer P, Elshaug C, Leslie E, Toumbourou JW, Patton GC, Williams J. Physical activity, leisure-time screen use and depression among children and young adolescents. J Sci Med Sport 2014;17:183-7.
8. Shape of the nation report: status of physical education in the USA. Reston, VA: National Association of Sports and Physical Activity & American Heart Association; 2012.
9. Weatherson KA, Gainforth HL, Jung ME. A theoretical analysis of the barriers and facilitators to the implementation of school-based physical activity policies in Canada: a mixed methods scoping review. Implement Sci 2017;12:41.
10. Dobbins M, Husson H, DeCorby K, LaRocca RL. School-based physical activity programs for promoting physical activity and fitness in children and adolescents aged 6 to 18. Cochrane Database Syst Rev 2013:CD007651.
11. Mei H, Xiong Y, Xie S, et al. The impact of long-term school-based physical activity interventions on body mass index of primary school children - a meta-analysis of randomized controlled trials. BMC Public Health 2016;16:205.
12. Taveras EP, M; Gerber, M; Whooten R. Effectiveness of Before School Physical Activity on Childhood Obesity Prevention: The BOKS Program. The Obesity Society2017.
13. 2010 Census. US Census. 2017, at http://www.factfinder.census.gov/.)
14. 2011-2015 American Community Survey 5-Year Estimates. US Census Bureau. 2017, at http://www.factfinder.census.gov/.)
15. Revere Public School District. 2016. at http://profiles.doe.mass.edu/reportcard/districtreportcardoverview2015.aspx?linkid=106&orgcode=02480000&fycode=2016&orgtypecode=5&.)
16. Revere Community Health Indicators: Massachusetts General Hospital Center for Community Health Improvement; 2017.
17. Kuczmarski RJ, Ogden CL, Grummer-Strawn LM, et al. CDC growth charts: United States. Adv Data 2000:1-27.
18. Gershon RC, Wagster MV, Hendrie HC, Fox NA, Cook KF, Nowinski CJ. NIH toolbox for assessment of neurological and behavioral function. Neurology 2013;80:S2-6.
19. Hillman CH, Pontifex MB, Castelli DM, et al. Effects of the FITKids randomized controlled trial on executive control and brain function. Pediatrics 2014;134:e1063-71.
20. Pontifex MB, Saliba BJ, Raine LB, Picchietti DL, Hillman CH. Exercise improves behavioral, neurocognitive, and scholastic performance in children with attention-deficit/hyperactivity disorder. J Pediatr 2013;162:543-51.
21. Doebel S, Zelazo PD. A meta-analysis of the Dimensional Change Card Sort: Implications for developmental theories and the measurement of executive function in children. Dev Rev 2015;38:241-68.

22. Varni JW, Burwinkle TM, Seid M, Skarr D. The PedsQL 4.0 as a pediatric population health measure: feasibility, reliability, and validity. Ambul Pediatr 2003;3:329-41.
23. Lum S, Bountziouka V, Harding S, Wade A, Lee S, Stocks J. Assessing pubertal status in multi-ethnic primary schoolchildren. Acta Paediatr 2015;104:e45-8.
24. Chervin RD, Hedger K, Dillon JE, Pituch KJ. Pediatric sleep questionnaire (PSQ): validity and reliability of scales for sleep-disordered breathing, snoring, sleepiness, and behavioral problems. Sleep Med 2000;1:21-32.
25. Davison KK, Falbe J, Taveras EM, et al. Evaluation overview for the Massachusetts Childhood Obesity Research Demonstration (MA-CORD) project. Child Obes 2015;11:23-36.
26. Davison KK, Cutting TM, Birch LL. Parents' activity-related parenting practices predict girls' physical activity. Med Sci Sports Exerc 2003;35:1589-95.